

## Cell Therapy Services



**FACILITY:** Cell therapies are processed in spatially segregated, dedicated ISO 7 (class 10,000) cell expansion rooms. The rooms contain biosafety cabinets, cold storage, CO<sub>2</sub> incubators and centrifuges. If requested, our controlled rate cell freezer can be used to carefully freeze cells. Cells are stored in validated ultra-low liquid nitrogen vapor phase freezers which are continuously monitored.

Process development for cell therapy processes is available. Process development activities are carried out on our 5,000 sq. ft. laboratories in a building adjacent to the cGMP facility.

**IN-HOUSE QUALITY CONTROL AND QUALITY ASSURANCE:** QC provides facility environmental monitoring procedures and a full battery of analytical methods. QA provides audited Production Batch Records, process monitoring and appropriate regulatory documentation, and CMC support for IND preparation.

**EXPERIENCE:** Florida Biologix scientists have experience optimizing, culturing and expanding many types of primary cells, including:

- Mesenchymal stem cells
- Lymphocytes
  - T-cells, CD4, CD8
- Dendritic cells
- Transfected T-cells

We can process autologous, allogeneic material or tissue from various sources such as whole blood, bone marrow, apheresis or cord blood.

Specialized or custom media is prepared in-house.

All cells are manufactured and tested in compliance with cGMP regulations and FDA regulatory agency requirements. Tests may include sterility, surface markers, functionality and viability.

Standardized procedures ensure no chance of mixing patient material. Our shipping experts make sure your product is delivered viable and on your schedule.

**FACILITY:** *The Florida Biologix 16,000 sq. ft. state-of-the-art manufacturing facility in Alachua, FL was designed and built to accommodate the simultaneous production of multiple cGMP products. The facility has been commissioned and fully calibrated with all systems and equipment qualified.*